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Policy

Policy and Guidelines for Interactions between the Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries ("Industry")

Date of implementation: October 1, 2006

Revised as of July 22, 2010

Purpose of Policy

The purpose of this policy is to establish guidelines for interactions with Industry representatives throughout the Stanford University Medical Center (SUMC), which is composed of the Stanford School of Medicine, Stanford Hospital and Clinics and the Lucile Packard Children's Hospital. Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and hospital and research equipment and supplies on-site, on-site training of newly purchased devices, the development of new devices, educational support of medical students and trainees, and continuing medical education. Faculty and trainees also participate in interactions with Industry off campus and in scholarly publications in a variety of circumstances

including consulting activities of various sorts. Many

aspects of these interactions are very positive and important for promoting the educational, clinical and research missions of the Medical Center and for translating knowledge and expertise from the faculty to society. However, these interactions must be ethical and cannot create conflicts of interest (COI) that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the institution. Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from any company. It is unacceptable for patient care decisions to be influenced by the possibility of personal financial gain.

Statement of Policy

It is the policy of the Stanford School of Medicine, Stanford Hospital and Clinics and the Lucile

» Purpose of Policy

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» Scope of Policy

- » Gifts and compensation
- » Site access by sales and marketing representatives
- » Provision of scholarships and other educational funds to students and trainees
- » Support for educational and other professional activities
- » Disclosure of relationships with industry
- » Training of students, trainees, and staff regarding potential conflict of interest in industry interactions


Packard Children's Hospital that interactions with Industry should be conducted so as to avoid or minimize conflicts of interest. When conflicts of interest do arise they must be addressed appropriately, as described herein.

Scope of Policy

This policy incorporates the following types of interactions with Industry.

- I. Gifts and compensation
- II. Site access by sales and marketing representatives
- III. Provision of scholarships and other educational funds to students and trainees
- IV. Support for educational and other professional activities
- V. Disclosure of relationships with industry
- VI. Training of students, trainees, and staff regarding potential conflict of interest in industry interactions

For purposes of this policy, "faculty" is defined as all members of the Academic Council [University Tenure Line, Non-tenure Line (Research), Non-tenure Line (Teaching) and Non-tenure Line (Clinical)], the Medical Center Line, the Clinician Educator Line and Adjunct Clinical Faculty. All faculty are required to comply with this policy at all times whether they are full time or part time.

In addition, Academic Council and Medical Center Line faculty must all comply with the Stanford University Faculty Policy on Conflict of Commitment and Interest. Clinician Educator Line faculty must comply with the  Stanford University Staff Policy on Conflict of Interest and Commitment. Additional information specifically related to industry interactions involving ACCME – accredited educational activities (also called CME) can be found at <http://cme.stanford.edu/policies/commercialsupport.html>. This policy also does not address relationships with other entities that are not encompassed by "Industry."

I. Gifts and Compensation

- A. Medical staff, faculty, staff, students, trainees and employees may not accept gifts from Industry anywhere at the Stanford School of Medicine, Stanford Hospital and Clinics, the Lucile Packard Children's Hospital, the Menlo Clinic or at any other clinical facility operated by either hospital, such as the LPCH Pediatric Unit at El Camino Hospital. Philanthropic gifts may only be accepted through the Office of Medical Development or the Office of Hospital Development.
 1. It is strongly advised that no form of personal gift from Industry be accepted under any circumstances. Individuals should be aware of other applicable policies, such as the AMA Statement on Gifts to Physicians from Industry and the Accreditation Council for Continuing Medical Education Standards for Commercial Support.
 2. Free drug samples are considered gifts under this policy and may not be accepted anywhere at the Stanford School of Medicine, Stanford Hospital and Clinics, the Lucile Packard Children's Hospital, the Menlo Clinic or at any other clinical facility operated by either hospital, such as the LPCH Pediatric Unit at El Camino Hospital.
- B. The following provisions apply to School of Medicine faculty, staff, students and trainees without limitation as to location. Gifts or compensation may not be accepted:
 1. At any non-Stanford-operated clinical facility such as other hospitals and outreach

clinics. However, no provision of this section shall apply to members of the ACF when engaged in patient-centered clinical activities unrelated to Stanford School of Medicine. Members of the ACF should be aware of other applicable policies, such as the 2010 AMA statement on physician use of drug samples ([Opinion 8.061 - Gifts to Physicians from Industry](#)) and the 2009 Institute of Medicine of the National Academies statement on [Conflict of Interest in Medical Research, Education, and Clinical Practice](#) and are strongly discouraged from accepting free drug samples since these are closely linked with marketing rather than professional activities.

2. For listening to a sales talk by an industry representative.
3. For prescribing or changing a patient's prescription.
4. For simply attending a CME or other activity or conference, including the defraying of costs (that is, if the individual is not speaking or otherwise actively participating or presenting at the event).

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II. Site Access by Sales and Marketing Representatives

- A. Sales and marketing representatives are not permitted in any patient care areas except to provide in-service training on devices and other equipment and then only by appointment.
- B. Sales and marketing representatives are permitted in non-patient care areas by appointment only. Appointments will normally be made for such purposes as:
 1. In-service training of Stanford Hospital and Clinic or Lucile Packard Children's Hospital personnel for research or clinical equipment or devices already purchased.
 2. Evaluation of new purchases of equipment, devices, or related items.
 3. Appointments for these purposes may be made on a per visit basis or as a standing appointment for a specified period of time, at the discretion of the faculty member, his or her division or department, or designated hospital personnel issuing the invitation and with the approval of appropriate hospital management.

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III. Provision of Scholarships and Other Educational Funds to Participants in School of Medicine Educational Programs

- A. Industry support of students and trainees in the School of Medicine educational programs should be free of any actual or perceived conflict of interest, must be specifically for the purpose of education and must comply with all of the following provisions:
 1. The School of Medicine department, program, division or institute selects the student or trainee.
 2. The funds are provided to the School, department, program, division or institute and not directly to the student or trainee or to an individual faculty member.
 3. The department, program, division or institute has determined that the funded conference or program has educational merit.

4. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a "quid pro quo"
 5. Notification of receipt of Industry support should be submitted at the time of receipt by the Office of the Associate Dean for Postgraduate Medical Education to the Office of the Senior Associate Dean for Medical Education, who will provide the Dean and the Conflict of Interest Review Program with an annual summary of this information for review.
- B. This provision does not apply to national or regional merit-based awards.

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IV. **Support for Educational and Other Professional Activities**

- A. All ACCME-accredited Continuing Medical Education (CME) activities (further described simply as CME) must be compliant not only with the [ACCME Standards for Commercial Support](#) but also with the [School of Medicine CME Commercial Support Policy](#). Effective September 1, 2008, new direct commercial funding for specific CME courses or programs is not allowed. However, support from industry for CME may be accepted by the Stanford Center for CME office in the following general areas of interest.

- 1-Medical, pediatric and surgical specialties
- 2-Diagnostic and imaging technologies and disciplines
- 3-Health policy and disease prevention
- 4-Other broadly defined topic areas

Such support cannot be designated for a specific course or program, but every effort is made to direct support, as appropriate, to the general area specified by the industry supporter. Further information may be found at

<http://cme.stanford.edu/policies/commercialsupport.html> and inquiries should be directed to the Stanford Center for Continuing Medical Education.

- B. All other School of Medicine educational events (non-CME) that are partially or fully supported by Industry must follow these guidelines:
1. Support from Industry may be accepted and managed by the department, program, division or institute but not by an individual faculty member.
 2. Industry supporters must sign Stanford's letter of agreement for educational activities.
 3. Support must be designated for a broadly defined topic (e.g., cardiology, psychiatry, neurosurgery) or recurring educational activity (e.g., grand rounds). Support may not be designated for a specific topic, speaker or activity.
 - a. "In kind" Industry support such as equipment and supplies may be designated to an activity
 4. Industry support for education must be spent exclusively on education.
 5. Industry support may not influence curriculum in any way.
 6. Industry exhibits are not permitted either on or off campus. Rare exceptions may be granted when a convincing argument is put forward that an industrial display is the

only means of realizing important educational goals. Such displays must be non-promotional in nature and exemptions to this policy require advance approval by the Associate Dean for Postgraduate Medical Education.

7. Industry promotion or marketing (e.g., corporate logos, slogans, signs, brochures, or other marketing materials) are not allowed.
 8. Industry employees will normally not serve as educators at such activities.
 9. When a faculty member has a financial interest that poses a content relevant conflict of interest, this should be disclosed to the learners.
 10. Receipt of industry support for educational activities for Stanford medical and graduate students and postdoctoral fellows and trainees must be reported at the time of receipt to the Senior Associate Dean of Medical Education.
- C. Meals or other types of food directly funded by Industry may not be provided at Stanford School of Medicine, Stanford Hospital and Clinics, the Lucile Packard Children's Hospital, or the Menlo Clinic or at Stanford-sponsored events off site.
- D. Meetings and conferences supported in part or in whole by Industry as they involve School of Medicine faculty, students, staff and trainees:
1. School of Medicine faculty, students, staff and trainees should evaluate carefully their attendance at meetings and conferences that are fully or partially sponsored or run by Industry because of the potential for perceived or real conflict of interest. They should be especially cognizant of this potential when considering whether to play a leadership role in such meetings and conferences by giving a lecture, organizing the meeting and the like. Except as noted below, these activities are allowed if the guidelines listed below are followed:
 - a. The activity is designed to promote evidence-based clinical care and/or advance scientific research;
 - b. Financial support by Industry is fully disclosed to the learners by the meeting sponsor.
 - c. The lecturer and not the Industry sponsor determines and prepares the meeting or lecture content.
 - d. The lecturer is expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse.
 - e. The Stanford participant is not required by an Industry sponsor to accept advice or services concerning speakers, content, etc., as a condition of the sponsor's contribution of funds or services.
 - f. When the lecturer is speaking as part of consulting activities, he or she makes clear that content reflects individual views and not the views of Stanford School of Medicine.
 - g. The use of the Stanford name in a non-Stanford event is limited to the identification of the individual by his or her title and affiliation.
 - h. Attendees do not receive gifts or other compensation for attendance.
 2. Participation in the following activities is not permitted:
 - a. Industry-sponsored "speakers bureaus" (i.e., contractual relationships to give talks in which the topic(s) and/or content are provided by the company).
 - b. Dedicated marketing and training programs designed solely or predominantly for sales or marketing purposes.

V. Disclosure of Relationships with Industry

- A. All faculty except Adjunct Clinical Faculty must complete on an annual basis the online Outside Professional Activities Certification System (OPACS) for posting in the School's publicly accessible Community Academic Profiles (CAP) system.
- B. In addition, all faculty engaged in clinical care activities except Adjunct Clinical Faculty must disclose on an annual basis through the online Outside Professional Activities Certification System (OPACS) any financial relationship with a company, entity, or third party that produces, manufactures, or distributes a medical device, implant, pharmaceutical or other medical care-related product that they recommend or prescribe to their patients.
- C. Adjunct Clinical Faculty must sign an attestation on an annual basis that they understand and comply with this policy.
- D. The following provisions about scholarly and educational activities apply to School of Medicine faculty, students, staff and trainees.
 1. Individuals are prohibited from engaging in ghostwriting; in other words, individuals may not publish articles under their own names that are written in whole or material part by industry employees.
 2. In scholarly publications, individuals must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors (www.icmje.org). In scholarly and public presentations faculty should disclose all relevant personal financial interests when appropriate.
 3. If a faculty member is listed as an author on any publication resulting from performance of their consulting services, the following disclosure must be made in the publication: Dr. [NAME]'s contribution to this publication was as a paid consultant to [COMPANY NAME]. Dr. [NAME] is not providing this material as part of his/her Stanford University duties or responsibilities." The same disclosure policy applies to speaking activities resulting from performance of consulting services.
 4. Faculty with teaching or supervisory responsibilities for students, residents, trainees or staff should ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her teaching or the supervision of the student, resident, trainee, or staff member.
- E. Individuals having a direct role making institutional decisions on equipment or drug procurement must disclose to the purchasing unit or selection committee, prior to making any such decision, any financial interest they or their immediate family have in companies that might substantially benefit from the decision. Additional policy concerning procurement activities at the hospitals can be found in hospital and medical staff policy documents. The purchasing unit, following the applicable guidelines, will decide whether the individual must recuse him/herself from the purchasing decision.

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VI. Training of Students, Trainees and Staff Regarding Potential Conflict of Interest in Interactions with Industry

All School of Medicine students, residents, and trainees will receive this policy document as well as training regarding potential conflict of interest in

interactions with industry. School of Medicine staff will receive a copy of this policy document in their initial employment materials.

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This policy will be modified as necessary in the future to be in compliance with requirements of external agencies.

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